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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,904	09/10/2001	Dennis Murphy	P50869	3015

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/889,904	MURPHY et al.
Examiner	**Art Unit**
Cybille Delacroix-Muirheid	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 10, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-4 and 6* is/are rejected.

7) ☒ Claim(s) *5, 7, and 8* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

The following is responsive to the Preliminary amendment received Sep. 10, 2001.

No claims are cancelled. New claims 7-8 are added. Claims 1-8 are presented for prosecution on the merits.

Claim Objections

1. Claims 1, 3, 4 are objected to because of the following informalities: in claim 1, line 3, "such" should be deleted and replaced with --said-- or --the--. In claim 3, line 2, "such" should be deleted and replaced with --said-- or --the--. In claim 4, line 2, "such" should be deleted and replaced with --said-- or --the--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 4 recites the limitation "gonadotropin" in line 3. There is insufficient antecedent basis for this limitation in the claim.

4. Claims 1-4 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for NK-3 antagonists, does not reasonably provide enablement for all compounds capable of inhibiting androgen or LH production. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The claims are drawn to inhibiting androgens, i.e. testosterone production and LH production by administering any compound which inhibits the production of androgens, testosterone or LH.

(2) The state of the prior art

The compounds of the invention can by any compound which has the above inhibitory activity. The art discloses known numerous compounds that have such an activity, all of them differing structurally and chemically.

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical art is high.

(5) The breadth of the claims

The claims are very broad and encompass any compounds, known or yet undiscovered, that are or may be capable of inhibiting the production of androgens (testosterone) and LH.

(6) The amount of direction or guidance presented

Applicant's specification provides guidance for and is only enabled for the use of NK-3 antagonists in the inhibition of androgens or LH. However, the specification provides no guidance, in the way of written description, to enable one of ordinary skill in the art to use the invention commensurate in scope with the claims. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The NK-3 antagonists described in the specification are not representative of the numerous compounds embraced by Applicant's claims.

(7) The presence or absence of working examples

As stated above, the examples in Applicant's specification describe using NK-3 antagonists for inhibiting androgen or LH production. Therefore, the specification enables one of ordinary skill in the art to use of NK-3 antagonists only in the claimed methods.

(8) The quantity of experimentation necessary

Since the significance of compound structure and activity for pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine the chemical structure of all of the compounds which would be capable of carrying out the claimed methods.

It is respectfully suggested that Applicant amend the claims to include administration of neurokinin-3 receptor antagonists.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartsch et al. (Abstract).

Bartsch et al. disclose a method of administering cyproterone acetate, an antiandrogen, to men with benign prostatic hyperplasia. The administration of this antiandrogen decreased testosterone and gonadotropin (LH) levels. Please see the abstract submitted herewith.

7. Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt et al. (Abstract).

Schmidt et al. teach a method of treating acne in male and female patients, the method comprising topically administering the antiandrogen, 17.alpha-propylmesterolone. Please see the abstract submitted herewith.

8. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Labrie et al. (Abstract).

Labrie et al. disclose a method of decreasing serum testosterone by administering to men an antiandrogen and an LHRH agonist. Please see the abstract submitted herewith.

9. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Labrie et al. (Abstract).

Labrie et al. disclose a method of treating prostate cancer in men, the method comprising administering a combination of an antiandrogen and LHRH agonist. The LHRH agonist caused a decrease in serum testosterone. Labrie et al. teach that the combination therapy "neutralizes androgens from all sources" and serves to minimize the development of metastases. Please see the abstract submitted herewith.

10. Claims 1, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Labrie 5,610,150.

Labrie discloses a method of treating prostate cancer in humans, the method comprising administering a therapeutically effective amount of an antiandrogen. Please see col. 3, lines 61-67.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

11. Claims 1, 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Golbs et al., 5,910,493.

Golbs et al. teach methods of treating acne, androgenically conditioned alopecia and androgenic symptoms of women, the methods comprising topically administering a pharmaceutical composition comprising the anti-androgenically acting gestogen, dienogest, or a combination of dienogest and an estrogen. Please see col. 2, lines 41-48; col. 6, lines 8-13.

12. Claims 1-4, 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Elbrecht et al., 5,872,150.

Elbrecht et al. disclose methods for treating BPH, prostatic carcinoma and prostatitis, the methods comprising administering effective amounts of the antiandrogenic compound represented by Formula I. Please see col. 1, lines 20-38. Furthermore, Elbrecht et al. teach that antiandrogens may also be useful in treating other hyperandrogenic diseases such as acne, hirsutism and androgenetic alopecia which includes male and female pattern baldness. See col. 2, lines 51-58.

In the background of the invention, Elbrecht et al. discloses that GnRH agonists, which are used in the treatment of prostatic cancer, are androgen-suppressing agents that reduce the production of testosterone. Col. 3, lines 38-50. Elbrecht et al. also teach that progestogens, used in the treatment of BPH, depress testosterone by inhibiting LH release and blocking androgen receptors. Col. 3, lines 52-55.

Allowable Subject Matter

13. Claims 5, 7-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1-4, 6 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

Dec. 17, 2001

Cybille Delacroix-Muirheid
Patent Examiner Group 1600